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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,231	07/29/2005	May Griffith	OSLER1100	1560

28213 7590 03/25/2009

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EXAMINER	
SCHUBERG, LAURA J	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
03/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,231	GRIFFITH, MAY	
	Examiner	Art Unit	
	LAURA SCHUBERG	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *12-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to papers filed 01/08/2009.

Claims 1-27 are pending. Claim 1 has been amended and no claims have been canceled or newly added.

Claims 12-26 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/5/2007.

Claims 1-11 and 27 have been examined on the merits.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 7-9, 11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (US 2002/0090725 A1).

Simpson teaches the formation of an engineered tissue using collagen, as an extracellular matrix, with cells and synthetic matrix materials that include poly(acrylic acid) and other similar synthetic polymers (page 4 para 63). Combinations of different types of cells can be used (page 5 para 66) and can be deposited within or on the matrices (page 5 para 65). The types of cells include neurons (nerve cells) and non-nerve cells (page 8 para 92-page 9 para 92). Addition of bioactive factors is included as well (page 9 para 97-98). The ability to use the matrices to bioengineer tissue or organs is suggested and corneas are listed as examples of bioengineered components (page 24 para 204). Nerve growth factor is taught as an optional additive to cause innervation of the tissue matrix after implantation (page 25 para 207). Using cells that are capable of growing as a confluent layer over the matrix is also suggested (page 35 example 15 and page 38 example 24). Derivatives of the biopolymer are taught as well (page 4 para 49). Simpson teaches that naturally occurring organic materials include any substances

naturally found in the body of plants or other organisms, regardless of whether those materials have or can be produced or altered synthetically (page 4 para 47). Forms of electroprocessed collagen include a hydrated gel (interpreted as a hydrogel) (page 14 para 129). Embodiments wherein the cells are distributed throughout the matrix are also included (page 20 para 179).

While Simpson does not combine all the limitations taught into a single embodiment, the claimed invention as a whole was prima facie obvious since all the claimed limitations are taught and suggested by the reference.

One of ordinary skill in the art would have been motivated and had a reasonable expectation of success in making these combinations to form the innervated artificial tissue as claimed by Applicant because they are taught and suggested by the reference as reasonable additives to the composition.

Therefore, the teaching of Simpson renders obvious Applicant's invention as claimed.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (US 2002/0090725 A1) as applied to claims 1-3, 7-9 and 11 and 27 above, and further in view of Chaouk et al (US 6,225,367 B1), Moussy et al (US 6,497,729 B1) and Clapper et al (US 6,514,734 B1).

Simpson suggests an innervated artificial tissue as described above, but does not specifically include wherein the synthetic polymers comprise the specific polymer

combinations of claims 4, 5, and 6. However, Simpson specifically teaches that many other synthetic polymers that may be developed are biologically compatible and include copolymers and blends and any other combinations of listed polymers (such as poly(acrylic acid)) with other polymers generally. The use of the polymers will depend on given applications and specifications required (page 5 para 63).

Chaouk teaches biocompatible polymers and products formed therefrom, including optical devices and implants (column 1 lines 1-5). N,N dimethyacrylamide is listed as a suitable polymer that is preferred (column 13 lines 1-9). The polymers of the invention are highly biocompatible with living tissue and support the attachment and growth of human or animal cells *in vivo* or *in vitro* (column 19 lines 47-50). The polymers of the invention are therefore particularly useful as medical implants such as corneal implants (column 19 line 56- column 20 line 2).

Moussy teaches a tissue/implant interface, comprising an implant and a bioactive polymer and indicates that N,N dimethyacrylamide, N-isopropylacrylamide and combinations thereof are suitable polymers that are preferred (column 5 lines 61-66). Acrylic acid is also taught as a suitable polymer (column 6 line 7). Exemplary implantation sites include, but are not limited to, the eye (column 12 line 3). Exemplary implants include, but are not limited to intraocular lenses, nerve regeneration channels, and corneal bandages (column 12 lines 5-15).

Clapper teaches bioactive polymers that are used to modify the surfaces of existing biomaterials or to generate new biomaterials. Biomedical devices that contain the resultant biomaterials are used for a variety of in vitro and in vivo applications such

as cornea lenses (column 11 lines 29-38). Suitable polymers are indicated as acrylic acid (column 4 line 63) and N-acryloxysuccinimide (column 19 line 28).

Therefore, one of ordinary skill in the art would have been motivated to use N,N dimethyacrylamide, N-acryloxysuccinimide, N-isopropylacrylamide, and acrylic acid in the method of Simpson because Simpson teaches that many other synthetic polymers may be developed that are biologically compatible and include copolymers and blends and any other combinations of listed polymers with other polymers generally and Chaouk, Moussy, and Clapper teach that these synthetic polymers are suitable for applications involving corneal implants. One of ordinary skill in the art would have had a reasonable expectation of success because Simpson, Chaouk, Moussy, and Clapper all include applications of suitable polymers for corneal implants and Simpson teaches that the use of the polymers will depend on given applications and specifications required (page 5 para 63).

Therefore, the combined teachings of Simpson, Chaouk, Moussy, and Clapper render obvious Applicant's invention as claimed.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (US 2002/0090725 A1) as applied to claims 1-9 and 11 and 27 above, and further in view of Jacob et al (US 2002/0007217 A1).

Claim 10 includes wherein the bioactive agent is a pentapeptide having the amino acid sequence YIGSR.

Simpson suggests an innervated artificial tissue as described above, but does not specifically include wherein the bioactive agent is a pentapeptide having the amino acid sequence YIGSR. However, Simpson does teach that several desirable sequences can be incorporated into synthetic collagen (such as RGD) and that any sequence that can be incorporated into a collagen molecule may be used (page 7 para 79).

Jacob teaches a synthetic polymer device for cornea augmentation and replacement which includes the form of a hydrogel. Jacob also includes short peptide sequences, such as YIGSR and RGD, that are responsible for cell-surface adhesion binding activity in extracellular adhesion proteins to be chemically incorporated onto polymer surfaces (page 5 para 30). Jacob teaches that these minimal binding sequences have only a fraction of the activity of the entire protein, yet their small size allows then to be incorporated at much higher concentrations than would be possible with entire proteins. The short peptide sequences have the advantage of being relatively stable and their synthetic nature renders them amenable to chemical derivatization and covalent attachment (page 5 para 30).

Therefore, one of ordinary skill in the art would have been motivated to add YIGSR peptide sequences to the innervated artificial tissue of Simpson because Jacob teaches that short peptide sequences, such as YIGSR and RGD, that are responsible for cell-surface adhesion binding activity in extracellular adhesion proteins can be advantageously incorporated onto polymer surfaces (page 5 para 30). One of ordinary

skill in the art would have also been motivated to include YIGSR in the tissue of Simpson because Jacob teaches that YIGSR and RGD have similar properties and functions and Simpson also teaches adding RGD. One of ordinary skill in the art would have had a reasonable expectation of success because Simpson also teaches that any sequence (besides RGD) that can be incorporated into a collagen molecule may be used as well (page 7 para 79).

Therefore, the combined teachings of Simpson and Jacob render obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments filed 01/08/2009 have been fully considered but they are not persuasive. Applicant's arguments have been addressed in so far as they relate to the rejections above.

Applicant argues that the Simpson reference does not include a matrix in the form of a hydrogel. Applicant asserts that there is no teaching or suggestion in Simpson of any innervated artificial tissue having functional nerve cells within a bio-synthetic hydrogel as required by the claimed invention.

This is not found persuasive because Simpson does in fact disclose gels as a form for the matrix, specifically hydrated gels which are interpreted as hydrogels (page 14 para 129). In addition Simpson also includes wherein the cells are distributed

throughout the matrix as well (page 20 para 179) and nerve cells and well as non-nerve cells (page 8 para 92-page 9).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/

Primary Examiner, Art Unit 1651

Laura Schuberg